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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/781,582	02/17/2004	Jane P. Bearinger	IL-11213	2811
7590		12/27/2007		
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			EXAMINER	
			NEAL, TIMOTHY J	
			ART UNIT	PAPER NUMBER
			3731	
			MAIL DATE	DELIVERY MODE
			12/27/2007	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

**Application No.**

10/781,582

**Applicant(s)**

BEARINGER ET AL.

**Examiner**

Timothy J. Neal

**Art Unit**

3731

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 21 September 2007.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1,4-6,11-17,19-21,25,31,32,34 and 35 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 4-6, 11-17, 19-21, 25, 31, 32, 34, and 35 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## DETAILED ACTION

This action is in response to the amendments filed on 09/21/2007.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

**Claims 1, 4, 11, 16, 17, 19-21, 31, 32, 34, and 35** are rejected under 35 U.S.C. 102(b) as being anticipated by Linden et al. (US 5,634,936).

Linden discloses a closure body (12) made of a SMP foam having at least one hard segment and one soft segment wherein the hard segment is formed at a temperature above  $T_{trans}$  and the soft segment is formed at a temperature below  $T_{trans}$  (Column 4 Line 7, product-by-process limitation), a primary shape (Figure 2), compressed into a reduced secondary shape (Figure 3), a delivery device being a catheter (20), an actuator means (Figure 4b), biodegradable polymers (Abstract), isocyanates (Column 6 Line 10), actuator means changing the temperature of the closure body above  $T_{trans}$  (Abstract). Linden also discloses positioning the closure body in a physical anomaly being a septal defect (Figure 4b). The SMP has the *ability* to do the newly added limitations. These limitations are functional and have been considered, but the prior art is considered capable of performing these limitations.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

**Claims 1, 4-6, 11-17, 19-21, 25, 31, 32, 34, and 35** are rejected under 35 U.S.C. 103(a) as being unpatentable over Linden et al. (US 5,634,936) in view of Michlitsch (US 2006/0155330) and Langer et al. (US 6,388,043) or Kamiya et al. (US 5,192,301).

Linden discloses a closure body (12) made of a SMP foam having at least one hard segment and one soft segment wherein the hard segment is formed at a temperature above  $T_{trans}$  and the soft segment is formed at a temperature below  $T_{trans}$  (Column 4 Line 7, product-by-process limitation), a primary shape (Figure 2), compressed into a reduced secondary shape (Figure 3), a delivery device being a catheter (20), an actuator means (Figure 4b), biodegradable polymers (Abstract), isocyanates (Column 6 Line 10), actuator means changing the temperature of the closure body above  $T_{trans}$  (Abstract). Linden also discloses positioning the closure body in a physical anomaly being a septal defect (Figure 4b). Linden does not explicitly disclose a plunger, backbleed tube, and restraint tube. Michlitsch teaches a plunger actuator (Fig 4A Item 20); a backbleed tube (Fig 4A Item 30) and a restraint tube (Fig 5B Item 74). Therefore, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify Linden's closure system to include

Michlitsch's plunger, backbleed tube, and restraint tube. Such modifications would allow the user to determine when the device has reached the closure site. The restraint tube is used to keep the closure plug in its proper location prior to delivery. The plunger is used to push the closure plug out of the delivery device. The Examiner considers the Linden reference to disclose the shape memory polymer as claimed. However, because the Applicant has traversed this rejection, the Examiner is providing an alternative rejection. Langer teaches a shape memory polymer foam that can be used in medical applications (Col 3 Line 1-20) including the polymers of claims 9 and 10 (Column 2 Lines 39-53). Langer further discloses that shape memory polymers have hard and soft segments formed at given temperatures (Col 3 Lines 1-20). Therefore, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify Linden's article to include Langer's shape memory polymer foam. Such a modification would provide a material that can be inserted into the body in one shape and then return to a predetermined shape upon heating. Kamiya also teaches shape memory polymers that recover at a given temperature (Abstract and Column 1 lines 40-45). The newly added limitations are also not sufficient to overcome the prior art. Simple logic would suggest that the closure body should be smaller than the gap it is to close upon entry into that gap. If this were not the case, the closure body would not fit into the gap in the first place. It must also follow logically that the closure body is larger than the gap once it has been placed into the gap. If this were not the case, the closure body would not close the gap. The above references teach the shape memory foam, its placement into a physical anomaly, and the device used to place it in

the anomaly. The references also teach that the plug changes shape upon temperature change. Therefore, the new limitations are not considered to overcome the prior art.

### ***Response to Arguments***

Applicant's arguments with respect to claims 1-35 have been considered but are moot in view of the new ground(s) of rejection.

The Applicant has merely stated that the prior art fails to show the features of the claims without pointing to any particular deficiencies. The Examiner will reiterate the arguments against patentability of this application as stated in the prior action. The claimed subject matter includes a known material claimed in a broad manner (shape memory polymer foam) used with a known delivery device (catheter, sheath, plunger, backbleed tube assembly) to perform a known technique (closing a defect or plugging a hole). Linden anticipates the claims as stated above by disclosing a shape memory polymer foam being used in the manner claimed. Michlitsch teaches the delivery device. The use and advantages of these devices are well known in the art. Also, Langer and Kamiya teach that the particular shape memory foam of the Applicant's claims is well known. Until the Applicant points to specific deficiencies, the rejections and prior art will remain.

### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Timothy J. Neal whose telephone number is (571) 272-0625. The examiner can normally be reached on M-F 9:00-5:30.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Todd Manahan can be reached on (571) 272-4713. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

TJN



Todd E. Manahan  
SPE 3731